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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,966	08/23/2001	James J. Rahal	13099	1546

7590 10/21/2003

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,966	RAHAL, JAMES J.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 and 7* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group II claims 5-9 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the examiner has not met the burden that two of more distinct inventions are presented. This is not found persuasive because the Office separated the treatment methods based on the different viral populations affected which would represent different patient population and would require different treatment protocols. Additionally, the office indicated that each of the compounds listed in the can also be used to treat separate patient population having different disease pathologies. Furthermore, applicants have presented the subcombinations (interferon alpha and ribivarin) separately in the indicating that the combination does not solely rely on either subcombination for patentability indicating that restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 5 and 7, are attached to the instant Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crance et al. (Travaux, 1999, see applicants IDS) in view of Albrecht et al. (U.S. Pat. No. 6,387,365).

The instant claims are drawn to a method of treating or preventing West Nile virus infection in an animal using an effective amount of interferon alpha-2b.

Crance et al. disclose the effect of known antiviral agents on a select group of flaviviruses including West Nile virus. The composition tested in the reference is interferon alpha-2b here the antiviral agent is added to the cell line at the same time the virus is added. Table 1 indicates that treatment at a dose of 10 IU /ml is sufficient to inhibit West Nile cyotpathogenic effect. The reference does not administer the antiviral compound to a patient, however, the reference indicates that this is the goal of the study.

Albrecht et al. teaches the use interferon alpha-2b for the treatment of chronic hepatitis C a flavivirus. In prior treatment of chronic hepatitis C infection with .alpha.-IFN monotherapy, .alpha.-IFN has been administered in dosages of about 3 to 10 million International units (IU) thrice weekly. Alternatively 3 to 10 million IU of .alpha.-IFN has been administered QOD (every

other day) or daily. The duration of the prior dosages has been from 12 to 24 months. This amount and duration of .alpha.-IFN monotherapy alleviates symptoms of hepatitis C in some of the patients, but it causes undesirable side effects, e.g. flu-like symptoms, in some (see column 2 lines 23-31). The preferred method of administering the .alpha.-IFN is parenterally, preferably by subcutaneous, IV, or IM, injection (see column 2, lines 55-56). The reference does not teach treating West Nile virus infection with interferon alpha-2b.

It would have been obvious to one of ordinary skill in the art to apply the interferon alpha-2b monotherapy treatment as taught by Albrecht et al. to the treatment of West Nile virus infection as taught by Crance et al. One having ordinary skill in the art would have a high expectation of success in administering interferon alpha-2b to a patient with West Nile virus in view of the teaching of Crance et al. which indicates that interferon alpha-2b is highly effective at preventing viral replication in the cell culture as established by the reduction of the cytopathic effect. Since the interferon alph-2b treatment can be administered at sufficient doses to achieve an effective treatment *in vivo* in a human patient with hepatitis C infection, another flavivirus infection, the ordinary artisan would have a high expectation of success in applying the same antiviral agent to a West Nile virus infection *in vivo*. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Albrecht et al. teaches administering the interferon alpha-2b monotherapy at a dose of 3-10 million units per day. Optimizing experimental conditions, including the timing of administering the compound, falls within the skills of an ordinary artisan. If the timing of adding the administering compound produces an unexpected result, applicant

needs to point out what the unexpected results are. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). Therefore, the instant invention is obvious over Crance et al. (Travaux, 1999, see applicants IDS) in view of Albrecht et al.

Conclusion

No claims allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Crance et al. Antiviral substances inhibiting in vitro replication of several arboviruses (Bunyaviridae, Flaviviridae, Togaviridae. Travaux Scientifiques des Chercheurs du Service de Sante des Armees (1996) Vol. 0, No. 17, pages. 57-58.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 10/22/03